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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/642,660	08/22/2000	Jonathan Schneck	01107.00042	9271

7590 10/03/2002  
Banner & Witcoff Ltd  
1001 G Street NW  
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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT PAPER NUMBER

1642

DATE MAILED: 10/03/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/642,660

Applicant(s)

SCHNECK ET AL.

Examiner

Christopher H Yaen

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 July 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 28-32 and 51-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-32 and 51-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. The examiner of the application has changed. This case has now been transferred as of 9/10/02. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Christopher Yaen, Group Art Unit 1642.
2. The amendment filed 6/26/02 (paper no. 10) is acknowledged and entered into the record.

#### ***Claim Rejections Withdrawn***

3. The rejection of claims 32, 56-58, and 60 under 35 USC § 112, 2<sup>nd</sup> paragraph as being indefinite is withdrawn in light of the arguments and amendments to claim language.

#### ***Claim Rejections Maintained***

4. The rejections of claims 56 and 57 under 35 USC § 112, 2<sup>nd</sup> paragraph as being indefinite is maintained for the reasons of record. The arguments presented by the applicant have been carefully considered but have not been found persuasive for the following reasons. Regarding the term "actively bound", applicant points to page 19, lines 10-13 of the specification, wherein the specification describes a method of obtaining "active binding", but does not provide to one of skill in the art what is to be encompassed by the term. Because it cannot be determined from the specification what is encompassed by the term, the metes and bounds of the term cannot be determined. Regarding the term "passively bound", applicant points to pages 28 and 29

Art Unit: 1642

of the specification wherein applicant contends that the metes and bounds of the term "passively bound" is clearly outlined, by providing an excerpt of a methodological step. Although the applicant is entitled to be his/her own lexicographer, one of skill in the art would find it difficult to obtain the exact definition of the term "passively bound" from this excerpt, because the term is never mentioned. Because both of the terms "actively bound" and "passively bound" can be interpreted in numerous ways and because the specification has not specifically defined these terms, the metes and bounds of both terms cannot be adequately determined.

5. The rejection of the claims 28-32 and 51-60 under 35 USC §112, 1<sup>st</sup> paragraph as lacking an enabling disclosure, is maintained. Applicant's arguments have been carefully considered but are not found persuasive for the following reasons. Applicant argues that the specification does in fact teach how to make and how to use the instant invention, wherein the applicant points to page 22-23 of the specification. It is conceded to the applicant that methods of linking a protein or molecule to the surface of the cell are well known and are possible. However, the composition of the instant invention utilizes a peptide linker, which may or may not effect the functionality of the molecular complex. The sensitivity of proteins to alterations of even a single amino acid in a sequence are exemplified by Burgess et al (J of Cell Bio. 111:2129-2138, 1990) who teach that replacement of a single lysine residue at position 118 of acidic fibroblast growth factor by glutamic acid led to the substantial loss of heparin binding, receptor binding and biological activity of the protein. Because the specification has only provided working examples of a soluble molecular complex and not of a molecular

complex linked at the surface of a cell through a peptide linker, it would be unpredictable to one of skill in the art as to whether such linkages would cause a loss of functionality to the fusion proteins of the molecular complex.

Applicant also argues that the specification teaches how to use the composition and that such teachings have been sufficiently detailed in the specification, wherein some of the uses include diagnostics, detection methods, and cell separation techniques. However, the specifications lack of details teachings the working examples for diagnostics or therapeutic uses forces one of skill in the art to experiment.

### ***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Art Unit: 1642

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen  
Art Unit 1642  
September 26, 2002

  
**BRENDA BRUMBACK**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**